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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,423	12/31/2001	Janette Lazarovits	10793/45	8825

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/032,423

Applicant(s)

LAZAROVITS ET AL.

Examiner

Karen A Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-163 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18-20, 23-27, 30, 34-49 and 155 is/are rejected.
- 7) ☒ Claim(s) 21, 22, 28, 29, 51, 53, 61, 68-72, 75-80, 82-86, 88, 96, 103-107, 110-115, 117 and 118 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/04 8/02 4/04 1/0</u> . | 6) <input type="checkbox"/> Other: ____. |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-17,31,33,50,52,54-60,62-67,73,74,81,87,89-95,97-102,108,109,116,119-154 and 156-163.

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DETAILED ACTION

Acknowledgment is made of applicant's election with traverse of Group III drawn to antibodies. The traversal is on the grounds that the restriction is improper as applicant contends that the claims of Groups III and IV can be searched together without serious burden on the examiner. Applicant further argues that once the antibodies of the invention are deemed novel and obvious, then methods of using said antibodies in the treatment of disease would also be novel and unobvious. This has been considered but not found persuasive. Both Groups III and IV are drawn to antibodies, not antibodies and methods of treating diseases comprising the administration of said antibodies. Further, Groups III and IV are linking claims. As stated in the Restriction Requirement of X/Y/Z, "upon allowance of the linking claims, the restriction requirement of the linked invention shall be withdrawn. Thus, when the elected claims are deemed free of the art and the restriction requirement between Groups III and IV will be withdrawn. The restriction requirement is deemed proper and adhered to. The restriction is therefore made **final**.

Claims 1-163, are pending. The submission of a properly numbered claim set including a separate claim number for new claim 23 which was included in the previous claim set as part of claim 22 is noted. Accordingly, the elected group reads on claims 18-30, 34-49, 51, 53, 61, 68-72, 75-80, 82-86, 88, 96, 103-107, 110-115, 117, 118 and 155. Claims 1-17, 31, 33, 50, 52, 54-60, 62-67, 73, 74, 81, 87, 89-95, 97-102, 108, 109, 116, 119-154 and 156-163, drawn to non-elected inventions, are withdrawn from consideration. It is noted that claim 32 (formerly claim 31) was included in this group as a typographical error because claim 32 is dependent on claim 31 which is part of group II. Claims 18-30, 34-49, 51, 53, 61, 68-72, 75-80, 82-86, 88, 96, 103-107, 110-115, 117, 118 and 155 are examined on the merits.

Priority

Acknowledgement is made of applicant's claim to an earlier effective priority date via provisional application 60/258,948. However, said provisional application, although providing a written description of antibodies comprising a first hypervariable region comprising a sequence selected from the group consisting of SEQ ID NO:8-24 and a second hypervariable region

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comprising a sequence selected from the group consisting of SEQ ID NO:1-6 and 125-202, does not provide any description of the genus of epitopes claimed, because disclosure of the CDR of antibodies does not provide a written description of the epitopes to which the antibodies bind. Further, the provisional application does not describe antibodies which bind to two different molecules selected from the group consisting of PSGL-1, fibrinogen gamma prime, GP1balpha, heparin, lumican, complement compound 4, interalpha trypsin inhibitor and prothrombin, or antibodies which inhibit cell-cell, cell-matrix, platelet-matrix, platelet-platelet or cell platelet interactions, or antibodies which inhibit cell rolling or autoimmune disease. The provisional fails to provide a written description of SEQ ID NO:203, on which the instant claim 23 depends. The provisional application states that Y1 bind to many leukemic cells and that Y17 binds to all cells tested including normal lymphocytes (page 105, Table 11), but said provisional does not disclose the epitope, protein or motif which is specifically bound by the antibody. Accordingly, claims 18-23, 25-30, 34-49, 51, 53, 61, 68-72, 75-80, 82-86, 88, 96, 103-107, 110-115, 117, 118 and 155 are given the effective priority date of the instant filing on December 31, 2001. Claim 24 will be given the effective priority date of the provisional application.

Claim Objections

Claims 38, 40-44, 46 and 49 are objected to for lacking sequence identifiers.

Appropriate correction is required.

Claims 18-22 and 155 are objected to for being dependent on a non-elected claim.

Appropriate correction is required.

Claims 21, 22, 28, 29, 51, 53, 61, 68-72, 75-80, 82-86, 88, 96, 103-107, 110-115, 117, 118 are objected to for being improper multiple dependent claims. A multiple dependent claims, such as claims 11-13 and 25, cannot be the basis for further multiple dependent claims. Accordingly claims 21, 22, 28, 29, 51, 53, 61, 68-72, 75-80, 82-86, 88, 96, 103-107, 110-115, 117, 118 are withdrawn from further consideration.

Appropriate correction is required.

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Claim 24 is objected to for the typographical error including “or” before “SEQ ID NO:20”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 19, 23-25 and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18 and 19 are dependent upon claims 1 and 5 which recite “P is (A)_m(A)_n(X)_u or (X)_u(A)_n(A)_m or (A)_n(X)_u(A)_m or (A)_n(A)_m(X)_u or (X)_u(A)_m(A)_n or (A)_m(X)_u(A)_n”, wherein A is any negatively charged amino acid or L, I, P, F, S or G. It is unclear if the content of “(A)” must be identical for (A)_m and (A)_n or if the content of “(A)” can be independently selected from any negatively charged amino acid or L, I, P, F, S or G. For purpose of examination, both alternatives will be considered.

Claims 18 and 19 are dependent upon claims 1 and 5 which recite a formula comprising (W)_z-P-(Y*)_t-P, wherein *=(S)_r. It is unclear if the content of both “P”s must be identical or independently selected. For purpose of examination, both alternatives will be considered.

Claims 23 and 24 recite “having the binding capabilities” of the scFv antibody and the peptide or polypeptide comprising a first hypervariable region comprising SEQ ID NO:20. The metes and bounds of “binding capabilities” cannot be determined. It is unclear if applicant intends that the binding capabilities are limited to substrate specificity, or epitope specificity, or if the binding capabilities include having the same binding affinity in addition to the same substrate specificity. For purpose of examination, both alternatives will be considered.

The recitation of “peptide or polypeptide” in claim 25 lacks antecedent basis in claim 23.

Claim 36 is indefinite because it cannot be determined if said claim requires that the two epitopes be different. For purpose of examination the claim will be read as encompassing

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antibodies which bind to two of the same epitopes and antibodies which bind to different epitopes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18, 19, 23-27, 30, 34-49 and 155 are rejected under 35 U.S.C. 102(b) as being anticipated by Ward et al (Biochemistry, 1996, Vol. 35, pp. 4929-4938, reference of the IDS filed Jan 27, 2003).

Claim 18 is drawn to an antibody, antigen-binding fragment or complex thereof comprising at least one antibody or binding fragment thereof capable of binding to or cross reacting with the isolated epitope of claim 1, which is drawn to an epitope comprising Formula I, wherein said epitope is capable of being bound by an antibody, antigen-binding fragment thereof comprising a first hypervariable region comprising SEQ ID NO:20. Claim 19 is drawn to antibody, antigen-binding fragment or complex thereof comprising at least one antibody or binding fragment thereof capable of binding to or cross reacting with the isolated epitope of claim 5, which is drawn to an epitope comprising Formula II, wherein said epitope is capable of being bound by an antibody, antigen-binding fragment thereof comprising a first hypervariable region comprising SEQ ID NO:20.

Claim 23 is drawn to an antibody, antigen-binding fragment thereof or complex thereof comprising at least one antibody or binding fragment thereof having the binding capability of the antibody fragment of SEQ ID NO:203. Claim 24 is drawn to an antibody, antigen-binding fragment thereof or complex thereof comprising at least one antibody or binding fragment thereof having the binding capability of a peptide or polypeptide comprising the hypervariable region of SEQ ID NO:20. Claim 25 embodies the antibody, antigen binding fragment thereof or complex thereof of claims 23 or 24 wherein the peptide or polypeptide has a second hypervariable region comprising SEQ ID NO:115 and/or a third hypervariable region comprising

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SEQ ID NO:114. Claim 26 is drawn to an antibody, antigen-binding fragment thereof or complex thereof comprising at least one antibody or binding fragment thereof, that is capable of binding to a peptide or polypeptide epitope of about 3 to about 126 amino acids in length and comprising at least 2 acidic amino acids and at least one sulfated tyrosine residue. Claim 27 embodies the antibody, antigen-binding fragment thereof or complex thereof of claim 26, wherein the epitope further comprises a proline, leucine, isoleucine, serine, glycine or phenylalanine residue. Claim 30 is drawn to an antibody, antigen-binding fragment thereof or complex thereof comprising at least one antibody or binding fragment thereof that is capable of binding to at least two different molecules selected from the group consisting of PSGL-1, fibrinogen gamma prime, GPIb-alpha, heparin, lumican, complement compound 4, interalpha tyrosine inhibitor and prothrombin. Claim 34 is drawn to an antibody, antigen-binding fragment thereof or complex thereof comprising at least one antibody or binding fragment thereof that is capable of binding to at least two different molecules selected from the group consisting of PSGL-1, fibrinogen gamma prime, GPIb-alpha, heparin, lumican, complement compound 4, interalpha tyrosine inhibitor and prothrombin and is further capable of binding to an epitope on a lipid, carbohydrate, peptide, glycolipid, glycoprotein, lipoprotein and or LPS. Claim 35 embodies the antibody, antigen-binding fragment thereof or complex thereof claim 34 wherein the epitope on the lipid, carbohydrate, peptide, glycolipid, glycoprotein, lipoprotein and or LPS comprises at least one sulfated moiety.

Claim 36 is drawn to an antibody, antigen-binding fragment thereof or complex thereof comprising at least one antibody or binding fragment thereof that is capable of cross-reacting with two or more epitopes, each epitope comprising one or more sulfated tyrosine residues and at least one cluster of two or more acidic amino acids. Claim 37 is drawn to an antibody, antigen-binding fragment thereof or complex thereof comprising at least one antibody or binding fragment thereof of claim 36 that is capable of cross-reacting with PSGL-1. Claim 38 embodies the antibody, antigen-binding fragment thereof or complex thereof of claim 36 wherein said antibody or binding fragment thereof binds to QATEYDYFLPETE. Claim 39 embodies the antibody, antigen-binding fragment thereof or complex thereof of claim 36 wherein said antibody or binding fragment thereof is capable of cross-reacting with GPIb-alpha. Claim 40 embodies the antibody, antigen-binding fragment thereof or complex thereof of claim 36 wherein

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said antibody or binding fragment thereof binds to DEGDTDLYDYYPEEDTEGD, wherein at least one tyrosine residue is sulfated. Claim 41 embodies the antibody, antigen-binding fragment thereof or complex thereof of claim 39 wherein said antibody or binding fragment thereof binds to TDLYDYYPEEDTE, wherein at least one tyrosine residue is sulfated. Claim 42 embodies the antibody, antigen-binding fragment thereof or complex thereof of claim 39 wherein said antibody or binding fragment thereof binds to DEGDTDLYDYYP, wherein at least one tyrosine residue is sulfated. Claim 43 embodies the antibody, antigen-binding fragment thereof or complex thereof of claim 39 wherein said antibody or binding fragment thereof binds to YDYYPEE, wherein at least one tyrosine residue is sulfated. Claim 44 embodies the antibody, antigen-binding fragment thereof or complex thereof of claim 39 wherein said antibody or binding fragment thereof binds to TDLYDYYP, wherein at least one tyrosine residue is sulfated. Claim 45 embodies the antibody, antigen-binding fragment thereof or complex thereof of claim 36 wherein said antibody or binding fragment thereof is capable of cross-reacting with fibrinogen gamma prime. Claim 46 embodies the antibody, antigen-binding fragment thereof or complex thereof of claim 45 wherein said antibody or binding fragment thereof binds to EPHAETEDSLYPED, wherein at least one tyrosine residue is sulfated. Claim 47 embodies the antibody, antigen-binding fragment thereof or complex thereof of claim 36 wherein said antibody or binding fragment thereof is capable of cross-reacting with heparin. Claim 48 embodies the antibody, antigen-binding fragment thereof or complex thereof of claim 36 wherein said antibody or binding fragment thereof is capable of cross-reacting with CC4. Claim 49 embodies the antibody, antigen-binding fragment thereof or complex thereof of claim 48 wherein said antibody or binding fragment thereof binds to MEANEDYEDYEYDELPAK, wherein at least one tyrosine residue is sulfated.

Claim 155 is drawn to an antibody, antigen-binding fragment thereof or complex thereof comprising at least one antibody or binding fragment thereof that is capable of binding the epitope of claim 153, wherein said epitope comprises residues 276-282 of GP1b-alpha, wherein at least one of 276, 278 and 279 are sulfated, and wherein the binding is enhanced when the epitope further comprises residues 283-285 of GP1b-alpha.

Ward et al disclose antibody SZ2 which binds the epitope of Tyr-276 to Glu-282, YDYYPEE (4935, first column, lines 19-21) of GP1b-alpha, which fulfills the specific

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embodiment of claims 39, 40, 42 and 43 because the YDYYPEE epitope is comprised within the sequences of claims 40 and 41. The SZ2 antibody also fulfills the specific embodiments of claims 18 and 19 because the SZ2 antibody binds to an epitope comprising the sequence YDYYPEE which was disclosed by Ward et al to be 90% sulfated on Tyr 278 and 279 and 50% sulfated on Tyr 282, and because Ward et al disclose the peptide of DEGDSDLYDYPEEDTEGD (page 4930, first column, line 44) which fulfills the specific embodiments of claim 5 with (Y)r=0, because z=1, (W)z=Gly, P(first)=Asp-Thr-Asp as (A)n(X)u(A), P(second)=Leu as (A)n, wherein m and u=0, sulfo-Tyr, P(third) as (A)n=Asp, wherein m and u=0, t=2 and (Y)t=sulfo-Tyr-sulfo-Tyr, P(forth)=Pro-Glu-Glu-Asp as (X)u(A)n(A)m, wherein u and m=1 and n=2 and (X)u=Pro, (A)n=Glu and (A)m is Asp. Said epitope also fulfills the specific embodiment of claims 1 and 2 wherein z=0, P(first)=(A)n(X)u(A)m, wherein, n=u=m=1 and wherein (A)n=Asp, (X)u=Thr and (A)m=Asp; t=1 and (Y)t=sulfo-Tyr; and wherein P(second)=(A)m(A)n(X)u, wherein n and u are 0 and wherein (A)m is Asp.

The SZ2 antibody of Ward et al anticipates the specific embodiment of claims 23-25 because claims 23-25 are limited to an antibody, antigen-binding fragment thereof or complex thereof comprising at least one antibody or binding fragment thereof having "the binding capabilities of SEQ ID NO:203. SEQ ID NO:20 and SEQ ID NO:20, 114 and/or 115, respectively, rather than being limited to the antibodies comprising the structure of SEQ ID NO:203. SEQ ID NO:20 or SEQ ID NO:20, 114 and/or 115. Because the term "binding capabilities" is vague and indefinite, the SZ2 antibody which binds to the epitope of GP-Ib which comprises residues Tyr-276 to Glu-282, which is 90% sulfated on Tyr 278 and 279 and 50% sulfated on Tyr 282 is a "binding capability" of SEQ ID NO:203. SEQ ID NO:20 and SEQ ID NO:20, 114 and/or 115.

It would be inherent in the binding affinity of the SZ2 antibody that it would cross-react with epitopes comprising DEGDSDLYDYYP and TDLYDYYP, wherein at least one tyrosine residue is sulfated; and that it would cross react with fibrinogen-gamma prime, heparin, lumican, complement compound 4, and the epitopes of 38, 46 and 49 because the structure of the antibody determines its binding specificity and cross-reactivity. Further, the enhancement of the binding of the SZ2 antibody to the epitope comprising residues 276 to 282 would be enhanced by

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the presence of residue 283-285 of GPI-b-alpha because the structure of the SZ 2 antibody determines its binding affinity.

Further, Berndt et al (US 5,659,018) discloses

“One of the striking features of PSGL-1 is its similarity to the .alpha.-chain of platelet GP Ib. Both are sialomucins and each has immediately N-terminal to the mucin core a sequence rich in negatively-charged amino acids with three potential sulfated tyrosine residues” (column 5, lines 45-49).

This statement by Berndt et al provides evidence that the PSGL-1 comprises a similar sulfated epitope as that of GP-Ib.

Claims 18, 23-27, 30, 34-49 and 155 are rejected under 35 U.S.C. 102(b) as being anticipated by Snapp et al (Blood, 1998, Vol. 91, pp. 154-164, reference of the IDS filed Jan 27, 2003).

Snapp et al disclose the monoclonal antibody KPL1 which binds to amino acids residues 5-11 (YEYLDYD) of PSGL-1, wherein at least one tyrosine is sulfated (page 161, second column, lines 7-10, page 162, second column, lines 39-41 and page 157, first column, lines 10-12), thus fulfilling the specific embodiments of claims 37 and 38. The disclosure of KPL1 also fulfills the specific embodiments of claims 18, 26 and 27 because the epitope of YEYLDYD meets the limitations of claim 1 with z=0, m and u=0 and P(first) is (A)_n=Glu and P(second)=(A)_n(A)_m(X)_u, wherein n=1, m=1 and u=0 and therefore (A)_n=Leu and (A)_m=Asp, in addition the epitope has a leucine residue which fulfill claim 27. Snapp et al also disclose that the KPL1 antibody binds to human myeloma cells (page 160, second column, lines 8-10), thus fulfilling the specific embodiment of claims 23-25, specifying that the antibody have the same “binding characteristics” as that of SEQ ID NO:203, SEQ ID NO:20 and either of SEQ ID NO:203, SEQ ID NO:20 in combination with SEQ ID NO:15 and/or SEQ ID NO:14.

It would be inherent in the binding affinity of the KPL1 antibody that it would cross-react with epitopes comprising DEGDTDLYDYYPEEDTEGD and YDYYPEE, wherein at least one tyrosine residue is sulfated; it would also be inherent in the binding affinity of the KPL1 antibody that it would cross react with GP-Ib, fibrinogen-gamma prime, heparin, lumican and complement compound 4, because the structure of the antibody determines its binding specificity and cross-reactivity. Berndt et al (US 5,659,018) discloses

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“One of the striking features of PSGL-1 is its similarity to the .alpha.-chain of platelet GP Ib. Both are sialomucins and each has immediately N-terminal to the mucin core a sequence rich in negatively-charged amino acids with three potential sulfated tyrosine residues” (column 5, lines 45-49).

This statement by Berndt et al provides evidence that the PSGL-1 comprises a similar sulfated epitope as that of GP-Ib.

Claims 18-20, 23-27, 30, 34-49 and 155 are rejected under 35 U.S.C. 102(b) as being anticipated by Suiko (US 5,716,836).

The specific embodiments of the claims are set forth above.

Suiko discloses the MSY-2 antibody which binds to sulfated tyrosine (column 5, lines 4-11). Said antibody anticipates all the instant claims because it would bind to all the disclosed epitopes and cross react with proteins comprising sulfonated tyrosines.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

An obviousness-type double-patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. *In re Berg*, 140 F.3d, 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18, 19, 23-27, 30, 34-49 and 155 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 and 32-48 of copending Application No. 10/029,988. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are anticipated by the '988 claims because the multimers of the '988 application can bind the same epitopes as the instant antibodies and exhibit the same cross-reactivities.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 18, 19, 23-27, 30, 34-49 and 155 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 21 of copending Application No. 10/029,926. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the '926 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Roubey, Blood, 1994, Vol. 84, pp. 2854-2867

Arvieux et al, Blood, 1999, Vol. 93, pp. 4248-4255

Austin et al, Molecular Biology of the Cell, Nov. 2001, Suppl., page 62a, abstract no. 338.

Somers et al, Cell, 2000, Vol. 103, pp. 467-479.

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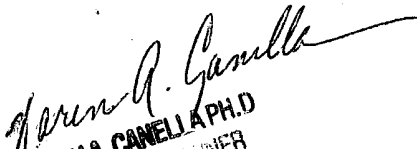
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

12/27/2004


KARENA CANELLA PH.D.
PRIMARY EXAMINER